UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,662	10/04/2006	J. Kern Buckner	0025.62/PCT-US	2433

25871 7590 09/30/2008

SWANSON & BRATSCHUN, L.L.C.
8210 SOUTHPARK TERRACE
LITTLETON, CO 80120

EXAMINER	
PORTER, JR, GARY A	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,662	BUCKNER ET AL.	
	Examiner	Art Unit	
	GARY A. PORTER, JR	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,13-15,17,19,20,26,29,34,36,40,43,44,46,59-62,68-71,75,78,80 and 89.* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 October 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/21/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-5,7,13-15,17,19,20,26,29,34,36,40,43,44,46,59-62,68-71,75,78,80 and 89.

DETAILED ACTION

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 2-5, 7, 20, 29, 44, 46, 59, 61 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Feld et al. (US Pub 2004/0002626).

2. Regarding claim 1, Feld teaches an apparatus implantable in a heart ventricle comprising a frame 60 configured to engage an inner circumferential periphery of a ventricle and to expand and contract between an expanded state corresponding to a desired end diastolic diameter of a ventricle and a contracted state corresponding to a desired end systolic diameter of the ventricle (Section [0027]); assisting means, i.e. an elastic property, operatively associated with the frame for mechanically assisting movement of the ventricle toward at least one of an end systolic diameter during systole and an end diastolic diameter during diastole; and means, i.e. spring 62, operatively associated with the frame for limiting an end diastolic internal diameter of the ventricle, since the spring is exerting a force limited by its properties of resiliency and elasticity (Section [0088, 0154-0156]; Fig. 11).

3. In regards to claim 2, Feld teaches that the assisting means, i.e. the elastic components of frame 60, assists movement of the ventricle toward both end systolic diameter during systole and end diastolic diameter during diastole (Section [0027]).

4. Regarding claim 3, Feld teaches that the assisting means assists movement of the ventricle toward only end diastolic diameter during diastole (Section [0155]).

5. Regarding claim 1, Feld teaches an apparatus implantable in a heart ventricle comprising a frame 14 (Fig. 4B; Section [0124]) configured to engage an inner circumferential periphery of a ventricle and to expand and contract between an expanded state corresponding to a desired end diastolic diameter of a ventricle and a contracted state corresponding to a desired end systolic diameter of the ventricle (Section [0027]); assisting means 12, i.e. an elastic member, operatively associated with the frame for mechanically assisting movement of the ventricle toward at least one of an end systolic diameter during systole and an end diastolic diameter during diastole (Section [0151]); and means 12 operatively associated with the frame 14 for limiting an end diastolic internal diameter of the ventricle, since the movement of the elastic members is limited its elasticity (Section [0151]; Fig. 10a).

6. In regards to claim 4, Feld teaches that the assisting means 12 is integrally formed with frame 14 (Fig. 4B).

7. With regards to claim 5, Feld teaches that the frame comprises a bistable element having a contracted stable state and an expanded stable state corresponding to a desired end systolic diameter and an end diastolic diameter, since the elastic arms

12 expand with a certain force and allow contraction to a certain point due to the elasticity of the arms 12 (Section [0027]).

8. In regards to claims 17 and 59, Feld teaches that the assisting means 12 comprises the frame being configured to self-bias between the expanded and contracted bistable states when circumferentially deflected beyond a select point toward the other of the bistable states. The elastic members will expand after the compressive force during systole begins to lessen. (Section [0027]).

9. With regards to claim 20, Feld teaches the frame and the assisting means comprise a resilient band 14; a spring element 12 operatively associated axially with the resilient band; and means for joining the ends of the resilient band into a circle, which is inherent since the band 14 is circular; the resilient band being configured, with the ends joined, to engage an inner circumferential periphery of a ventricle (Fig. 4B; Section [0037, 0124]), with the spring element in a relaxed state during one of an end diastolic or end systolic state of the ventricle (Section [0027]).

10. Regarding claim 29, Feld teaches a method of treating cardiac disease comprising surgically accessing a ventricle, inserting within the ventricle an apparatus configured to mechanically assist movement of the ventricle toward at least one of an end systolic diameter during systole and an end diastolic diameter during diastole and configured to limit an end diastolic internal diameter of the ventricle; and attaching the device to a portion of myocardium defining an inner circumferential periphery of the ventricle (Section [0027, 0156]).

11. In regards to claim 44, Feld teaches an apparatus implantable in a heart ventricle comprising a bistable element configured to engage an inner circumferential periphery of a ventricle, the bistable element having a contracted stable state and an expanded stable state corresponding to a desired end systolic diameter and diastolic diameter (Section [0027]).

12. With regards to claim 46, Feld teaches a means 12 operatively associated with the bistable element for limiting the expanded stable state of the bistable element, since the elastic arms expansion is limited by its elasticity (Section [0116]).

13. Regarding claim 61, Feld teaches a method of augmenting systolic contraction and diastolic relaxation of a heart ventricle comprising providing a bistable element configured to engage an inner circumferential periphery of a ventricle, the bistable element having a contracted stable state and an expanded stable state corresponding to a desired end systolic diameter and end diastolic diameter, respectively (Section [0027]); surgically accessing the ventricle; inserting the bistable element within the ventricle; and attaching the bistable element to a portion of myocardium defining the inner circumferential periphery of the ventricle (Section [0156]).

14. In regards to claim 62, Feld teaches limiting the expanded stable state of the bistable element, since the elasticity of arm 12 limits the expansion of the arm during diastole (Section [0027, 0080, 0118]).

15. Claims 1, 5, 7, 13-15, 19, 20, 26, 29, 34, 43, 44, 60, 68-71, 75, 78 and 89 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferrazzi (US Pub. 2003/0158570).

16. Regarding claims 1 and 19, Ferrazzi teaches an apparatus implantable in a heart ventricle comprising a frame 7 (Fig. 9) configured to engage an inner circumferential periphery of a ventricle and to expand, which the frame is capable of since it is a spring (Section [0075]), and contract between an expanded state corresponding to a desired end diastolic diameter of a ventricle and a contracted state corresponding to a desired end systolic diameter of the ventricle; assisting means 10 operatively associated with the frame for mechanically assisting movement of the ventricle toward at least one of an end systolic diameter during systole and an end diastolic diameter during diastole (Section [0081]); and means operatively associated with the frame 7 for limiting an end diastolic internal diameter of the ventricle (see claim 14). Furthermore, with respect to claim 19, Ferrazzi teaches that a biocompatible sheath surrounds the frame 7 and the assisting means 10 (Section [0082]).

17. With regards to claim 5, Ferrazzi teaches that the frame comprises a bistable element having a contracted stable state and an expanded stable state corresponding to a desired end systolic diameter and an end diastolic diameter, since the elastic members 10 and the rings 6, 7,and 8 expand with a certain force and allow contraction to a certain point due to the elasticity of the components (Section [0077]).

18. In regards to claim 7, Ferrazzi teaches the bistable element comprises a plurality of longitudinal bands 10 each having a top and a bottom end, the top ends of the

longitudinal bands being joined by a top circumferential band 6 extending there between and the bottom ends of the longitudinal bands being joined by a bottom circumferential band 8 extending there between (Fig. 9).

19. Regarding claim 13, Ferrazzi teaches that the bottom circumferential band is configured to perform as a spring (Section [0075]).

20. In regards to claim 14, Ferrazzi teaches a mitral annuloplasty ring 6 extending axially from a top of the bistable element 10, the bistable element 10 and the mitral annuloplasty ring 6 being configured so that with the bistable element 10 attached to myocardium defining the inner circumferential periphery of a left ventricle, the mitral annuloplasty ring is below but proximate the mitral annulus (Section [0071]). Furthermore, ring 6 is defined as a mitral annuloplasty due to its placement proximate the mitral annulus and its function of reestablishing annular dimension (Section [0001]).

21. With regards to claim 15, Ferrazzi teaches that at least one of the top and bottom circumferential bands is split across its circumference to define a C-shaped band (Section [0072-0073]).

22. Regarding claims 20 and 68, Ferrazzi teaches the frame and the assisting means comprise a resilient band 7; a spring element 8 operatively associated axially with the resilient band (Section [0075]); and means for joining the ends of the resilient band into a circle, which is inherent since the band 7 is circular; the resilient band being configured, with the ends joined, to engage an inner circumferential periphery of a ventricle, with the spring element in a relaxed state during an end diastolic state of the ventricle, since the band is not under compression in diastole (Section [0051]; Fig. 9).

Furthermore, specifically with respect to claim 68, Ferrazzi teaches a means operatively associated with the resilient band for limiting an end diastolic internal diameter of the ventricle (see claim 14).

23. In regards to claim 26, Ferrazzi teaches a mitral annuloplasty ring 6 extending axially of the resilient band 7 with the resilient band 7 formed into a circle (Fig. 9).

24. With regards to claim 29, Ferrazzi teaches inserting the device within the ventricle of the patient, therefore requiring surgically accessing the ventricle (Section [0068]), wherein the device is configured to mechanically assist movement of the ventricle toward at least one of an end systolic diameter during systole and an end diastolic diameter during diastole and configured to limit an end diastolic internal diameter of the ventricle (Section [0077]); and attaching the device to a portion of the myocardium defining an inner circumferential periphery of the ventricle (Section [0079]).

25. Regarding claim 34, Ferrazzi teaches that in the inserting step the apparatus comprises a resilient band 7 comprising at least one spring element operatively associated axially with the resilient band (Section [0075]) to allow axial stretching and compression of the resilient band, the inserting step further comprising placing the resilient band into contact with the inner circumferential periphery of the ventricle and forming the resilient band into a loop of a diameter about equal to an end diastolic diameter an inner circumferential periphery of the ventricle (Section [0077-0079]; Fig. 9).

26. In regards to claim 43, Ferrazzi teaches that the resilient band further comprises a mitral annuloplasty ring 6 extending axially of the resilient band 7 with the resilient

band 7 formed into a circle, the method further comprising attaching the mitral annuloplasty ring 6 to the myocardium below but proximate the mitral annulus (Fig. 9; Section [0001, 0071]).

27. With regards to claim 44, Ferrazzi teaches an apparatus implantable in a heart ventricle comprising a bistable element 7 configured to engage an inner circumferential periphery of a ventricle, the bistable element 7 having a contracted stable state and an expanded stable state corresponding to a desired end systolic diameter and diastolic diameter (Section [0077-0079]).

28. Regarding claim 60, Ferrazzi teaches that element 7 is elliptical in an expanded state (Section [0068]; Fig. 9). Examiner takes official notice that since element 7 is elastic, when the extremes of the elliptical element 7 that contact the ventricular wall are compressed in systole, the elliptical shape will deform into a generally hour-glass profile.

29. In regards to claim 69, Ferrazzi teaches a biocompatible sheath around the resilient band and spring element (Section [0082]).

30. With regards to claim 70, Ferrazzi teaches a means limiting the diameter of the resilient band during diastole (see claim 14).

31. Regarding claim 71, Ferrazzi teaches that the spring element is integrally formed of the resilient band (Section [0075]).

32. In regards to claim 75, Ferrazzi teaches a mitral annuloplasty ring 6 extending axially of the resilient band 7 with the resilient band 7 formed into a circle (Fig. 9).

33. With regards to claim 78, Ferrazzi teaches a method of treating cardiac disease comprising providing a resilient band 7 having at least one spring element operatively associated axially with the resilient band to allow axial stretching and compression of the resilient band (Section [0075, 0077-0079]) and means for limiting axial stretching of the resilient band since the bands are plastic in the axial direction (Section [0077]), surgically accessing a ventricle of a heart placing the resilient band into contact with the inner circumferential periphery of the ventricle (an inherent step as seen by the location of the device in Fig. 9); forming the resilient band into a loop of a diameter about equal to an end diastolic diameter of an inner circumferential periphery of the ventricle; and attaching the resilient band loop to the myocardium defining the inner circumferential periphery of the ventricle (Section [0077-0079]l Fig. 9).

34. Regarding claim 89, Ferrazzi teaches the resilient band further comprises a mitral annuloplasty ring 6 extending axially of the resilient band with the resilient band 7 formed into a circle (Section [0071]; fig. 9), the method further comprising attaching the mitral annuloplasty ring 6 to the myocardium below but proximate the mitral annulus (Section [0071]; fig. 9).

Claim Rejections - 35 USC § 103

35. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

36. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feld et al. (US Pub 2004/0002626) in view of Stevens et al. (US Patent 6,125,852). Feld discloses all of the claimed invention except for performing a surgical ventricular reduction. However, Stevens teaches that it is known in the art to perform a ventricular reduction on a congestive heart failure patient in order reshape the enlarged heart to a normal size (Abstract; Fig. 3-5). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Feld reference to include performing a surgical ventricular reduction, as taught and suggested by Stevens, for the purpose of reshaping an enlarged heart to a normal size.

37. Claims 36 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrazzi (US Pub. 2003/0158570) in view of Cloud (US Patent 5,184,482). Ferrazzi discloses a closed circular band placed within the heart (Fig. 3). Ferrazzi does not disclose a resilient band that includes at least one circumferential ligature operatively associated with the resilient band, the circumferential ligature having opposing free ends, the method further comprising: forming the resilient band into a loop by tying the opposing free ends of the ligature together. However, Cloud teaches forming a loop with a spring metal material by attaching free ends of the material together (col. 7, lines 40-59). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Ferrazzi reference to include a resilient band that includes at least one circumferential ligature operatively associated with the resilient band, the circumferential ligature having opposing free ends, the method further comprising: forming the resilient band into a loop by tying the opposing

free ends of the ligature together, as taught and suggested by Cloud, for the purpose of forming a closed loop spring that fits within the ventricle of the heart in order to promote diastolic expansion and systolic contraction.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY A. PORTER, JR whose telephone number is (571)270-5419. The examiner can normally be reached on Monday - Thursday, 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. A. P./
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766